JUL 1 3 2000

K001583

ISLAND BIOSURGICAL, LLC

Bladder Neck Suspension Kit
Island Biosurgical, LLC
510(k) Notification

510(k) SUMMARY

Contact Person: Hunter A. McKay, M.D.
Date: May 10, 2000
Trade Name: Island Biosurgical Bladder Neck Suspension Kit #3.
Common Name: Bladder Neck Suspension (BNS) Kit.
Classification Name: None available for the Kit
Predicate device: Island Biosurgical, Inc. Bladder Neck Suspension Kit #1.
Substantial Equivalence: This kit is substantially equivalent to the Island Biosurgical, Inc. BNS Kit #1.
Description: A surgical kit including disposable surgical suture carriers, implantable polypropylene mesh bolsters, a urethral Foley catheter, and surgical drapes.
Intended use: The Island Biosurgical, Inc. Bladder Neck Suspension Kit is to be used by operating pelvic surgeons to surgically correct female stress urinary incontinence due to pelvic relaxation and intrinsic sphincter deficiency.
Technological characteristics: Kit contains disposable surgical instruments (exempt - 876.4730), implantable bolsters (K960101), legally marketed surgical draping material and calibrated Foley urethral catheter.
Performance testing: Performance testing was not included in this 510(k).

Ref: \FDA\Kit3\SUMMARY.021

18 Meadow Lane
1-800-858-5359 Mercer Island, WA FAX 206/232-6239
98040-5340

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2000

Hunter A. McKay, M.D.
Manager
Island Biosurgical, LLC
18 Meadow Lane
Mercer Island, WA 98040-5340

Re: K001583
Bladder Neck Suspension Kit
Dated: May 10, 2000
Received: May 22, 2000
Regulatory Class: II
21CFR 876.5090/Procode: 78 KOD & FEW
21CFR 878.3300/Procode: 79 FTL

Dear Dr. McKay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Bladder Neck Suspension Kit
Island Biosurgical, LLC
510(k) Notification

APPENDIX C

INDICATIONS FOR USE STATEMENT

The Island Biosurgical, Inc. Bladder Neck Suspension Kit is to be used by operating pelvic surgeons to surgically correct female stress urinary incontinence due to pelvic relaxation or intrinsic sphincter deficiency.

Ref: \FDA\Kit3\Sec2C.001

David A. Krysan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001583

Prescription Use ✓
(Per 21 CFR 801.109)